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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,049	03/28/2002	Jorg Rosenberg	0480/01221	5165

26474 7590 08/14/2006

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/019,049	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37.CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 4-8.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1,3 and 9-19 are cancelled by the amendment filed 7/13/06. Claims 4-8 are pending. Applicant's argument that a) the prior art fails to teach paroxetine or its physiologically acceptable salt in the form of molecular dispersion in a pharmaceutically acceptable matrix material which comprises a completely synthetic polymer having a glass transition temperature of greater than 90 oC in the anhydrous state and that b) the prior art fails to teach paroxetine or one of its salts and the matrix material being mixed to give a homogeneous melt in an extruder, is not persuasive because Krape discloses solid dispersion of paroxetine in polyvinylpyrrolidone or polyethylene glycol (abstract; page 5, lines 31-34) and the mixture is heated to form a molten homogeneous melt of polymeric carrier and paroxetine free base (page 6, lines 37 and 38). It is noted that applicant's specification at page 1, lines 37-39) describe dispersions as molecular dispersion system; applicant's specification names polyvinylpyrrolidone as a preferred matrix material (page 3, line 18) and polyvinylpyrrolidone is a synthetic polymer; the glass transition temperature in an inherent characteristic/property of the polymer; while Krape does the melting in a flask, Remon is relied upon for forming pellets/particles in an extruder. In response to applicant's argument that Remon teaches the preparation of a wet mass, it is noted that on page 132, left column, lines 3-5 from the bottom specifically discloses that "the most popular method of producing pellets is by extrusion-spheronisation technique," and it is further noted that Remon describe the process of forming pellets from granulation to extrusion to spheronisation to drying (pages 133-137) so that the final product is not a wet mass. Remon also describes different types of extruders (section 2.2 at page 134). Furthemore, Krape discloses heat step to form a melt. It is further noted that. although applicant says that Remon does not disclose melt extrusion, it is Krape melts the mixture and forms particles and the process of Krape can be perfomed in an extruder instead of a flask in order to produce pellets according to Krape. There is no demonstration that the melt process of Krape cannot be done in an extruder. Regarding the temperatures in Krape and the instant claims, it is noted that Krape prepares particles of paroxetine formulation from paroxetine and poyvinylpyrrolidone and the instant claims prepares paroxetine particles from paroxetine and synthetic polymer, which according to applicant's specification is polyvinylpyrrolidone (page 3, linne 18) and as such it flows that the mixtures containing the same drug and polymer would respond to similar temperatures without adverse effects.